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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,115	06/23/2005	Ola Karlsson	1103326-0781	8848

7470 7590 10/06/2006

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PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

WU, IVES J

ART UNIT	PAPER NUMBER
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1724

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,115

Applicant(s)

KARLSSON ET AL.

Examiner

Ives Wu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,23-25 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 6 is/are allowed.
- 6) ☒ Claim(s) 1-4,7-16,23-25,27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

(1). Applicants' Amendments and Remarks filed on August 10, 2006 have been received.

Claim 26 is cancelled. Total cancelled claims are 17-22 and 26.

Claims 1-4, 7-9, 23 and 25 are amended.

Claims 5 and 6 are amended and incorporate with the limitation of claim 26.

The objection and rejection of claims 5 and 6 in prior Office Action dated April 10, 2006 is removed accordingly.

The allowance of claim 26 in prior Office Action dated April 10, 2006 is cancelled accordingly.

The rejections for claims 1-4,7-8,10-16,23-25,27-32 in the prior Office Action dated April 10, 2006 is sustained and presented with rejection of claim 9 in the paragraphs below.

Claim Rejections - 35 USC § 102

(2). The text of those Section Title 35 U.S. Code not included in this Office Action can be found in prior Office Action dated April 10, 2006.

(3). **Claims 1 – 4, 7 - 8, 23 - 24 and 31** are rejected under 35 U.S.C. 102(b) as being anticipated by Reinecke et al (US004056497) for the same rationale recited in prior Office Action dated April 10, 2006.

Claim Rejections - 35 USC § 103

(4). The text of those Section Title 35 U.S. Code not included in this Office Action can be found in prior Office Action dated April 10, 2006.

(5). **Claims 9 - 14 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497) and Barry et al (US005055306) for the same rationale recited in the prior Office Action dated April 10, 2006.

As to step of applying the aqueous dispersion to the surface of the dosage form and removing water from the aqueous dispersion to obtain film in a pharmaceutical coating film in **claim 9**, Barry et al (US005055306) disclose the coating being prepared by forming a solution and mixing it with a dispersion of a water insoluble but water swellable acrylic polymer. The

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aqueous mixture is then used to coat the dried granules, and the coated granules are subsequently dried (Col. 8, line 37-43). Obviously, the water is removed and film is formed after the coating is dried.

Barry et al **do not teach** the use of acrylic ester copolymer of Reinecke et al for the coating in pharmaceutical formulation.

The advantage of using the acrylic ester copolymer taught by Reinecke et al is pressure-sensitive adhesive of high heat stability (Abstract, line 6-7).

Therefore, it would have been obvious at time of the invention to use the acrylic ester copolymer of Reinecke et al et al for the coating film of pharmaceutical formulation of Barry et al in order to obtain the above-mentioned advantage. Moreover, the acrylic ester polymer taught by Barry et al is a genus, the acrylic ester copolymer taught by Reinecke et al is species, one ordinary skill in the art would expect all species work successfully for the genus, motivated by a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

(6). The same rationale of rejection for claims 10-14 and 25 are recited in prior Office Action dated April 10, 2006.

(7). **Claims 15 and 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497) and Barry et al (US005055306), in view of Chen (US005939578A), further evidenced by Jonsson et al (US004957745) for the same rationale recited in prior Office Action dated April 10, 2006.

(8). **Claims 27-30 and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinecke et al (US004056497) in view of Contrada et al (US006646046B2) and Zellstoffwerke (GB001141165) for the same rationale recited in prior Office Action dated April 10, 2006.

Allowable Subject Matter

(6). **Claims 5,6** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

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(7). Applicant's arguments filed on August 10, 2006 have been fully considered but they are not persuasive.

Applicants' amend the claims 1,2,3,4,7,8,23 by using "consisting essential of ", however, the prior art reference Reinecke et al (US004056497) disclose the acrylic ester copolymer composition is prepared before the crosslinking, it would not crosslink without alkalies (Abstract, line 5-6). Therefore, the acrylic ester copolymer composition still reads on the applicants' claims even though other ingredients may be added to prepare as an intermediate products and would not alter the characters of acrylic ester copolymer of Reinecke et al (US004056497) as long as crosslink (alkalies) is absent.

It is noticed that claims 7 and 8 are amended to become a product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on product itself. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 277 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ives Wu whose telephone number is 571-272-4245. The examiner can normally be reached on 8:00 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Examiner: Ives Wu

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Date: October 2, 2006

DUANE SMITH
PRIMARY EXAMINER

D. A.
10-2-06